

PATENT

Atty. Dkt. No. NEKT/0003

REMARKS

This is intended as a full and complete response to the Office Action dated April 5, 2005, having a shortened statutory period for response with a two month extension of time set to expire on September 5, 2005. Please reconsider the claims pending in the application for reasons discussed below.

Claims 20-39 and 41-80 remain pending in the application upon entry of this response. Claims 1-19 and 40 are cancelled by the Applicant. Claims 20-39 and 41-42 stand rejected by the Examiner. Claims 43-80 have been added by the Applicant. Reconsideration of the rejected claims is requested for reasons presented below.

Claims 20-39 and 41-42 stand rejected under 35 USC § 103(a) over *Bogentoft et al.*, U.S. Pat. No. 4,341,759 (herein *Bogentoft*). The Examiner asserts that the claimed invention would have been obvious to one skilled in the art at the time of the invention in view of *Bogentoft*. The Applicant respectfully traverses the rejection.

Bogentoft discloses large, time released particles that are formed by a spray coating process. The particles contain a core that is coated with a mixture to form a gradient concentration decreasing towards the surface. The core does not have a gradient concentration, only the coating has a gradient concentration. Figures 1a-1d of *Bogentoft* depict the core 1 without a change of concentration with respect to an increasing radius, while the applied layer 2 may have different permutations of concentration gradients with respect to an increasing radius.

Examples 1-3, as provided by *Bogentoft*, reveal a starting core material of granules with a size between 0.5 mm and 0.75 mm (500 μ m to 750 μ m) that are coated to produce particles with a final size between 0.75 mm and 1.0 mm (750 μ m to 1,000 μ m). Example 4 of *Bogentoft* reveals a starting core material of granules with a size between 0.75 mm and 1.0 mm (750 μ m to 1,000 μ m) that are coated to produce particles with a final size between 1.0 mm and 1.2 mm (1,000 μ m to 1,200 μ m). *Bogentoft* further discloses that the coated granules may have a size within a range from 0.1 mm (100 μ m) to 15 mm, preferably, from 0.1 mm to 1 mm.

Bogentoft, alone or in combination, does not teach, show or suggest a particulate coformulation of an active substance and an additive, which is a solid dispersion of one component in the other, but which has a finite gradient in a relative additive

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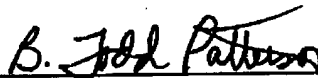
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concentration, which concentration increases radially outwards, which particulate coformulation comprises either spherical or approximately spherical particles having a volume mean diameter of less than 100 μm , or of needle-like particles having a volume mean length within a range from about 5 μm to about 100 μm and a volume mean thickness within a range from about 0.5 μm to about 5 μm , or of plate-like particles having a volume mean thickness within a range from about 0.5 μm to about 5 μm , as recited in claim 20, and claims 21-39 and 41-42 dependent thereon. Withdrawal of the rejection is respectfully requested.

In conclusion, the reference cited by the Examiner, alone or in combination, does not teach, show or suggest the claimed invention.

Having addressed all issues set out in the office action, the Applicant respectfully submits that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,



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